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PRIMA BIOMED GAINS BELGIAN REGULATORY APPROVAL TO COMMENCE A REGISTRATION PHASE IIB STUDY OF IMP321

- Belgium's Federal Agency for Medicines and Health Products approved the commencement of the AIPAC study
- IMP321 Phase IIb trial initiation is expected before the end of 2015

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SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD), a leading immuno-oncology company, is pleased to announce its first regulatory approval facilitating commencement of the landmark Phase IIb clinical study of IMP321, Prima's lead compound.

The AIPAC (Active Immunotherapy PAClitaxel) clinical trial application has been cleared by Belgium's Federal Agency for Medicines and Health Products (FAMHP). AIPAC is a multi-national, randomized, double-blind, placebo-controlled Phase IIb study of IMP321 in metastatic breast cancer which has received Scientific Advice from the European Medicines Agency (EMA). Prima continues work to obtain ethics approval by the Institutional Review Boards (IRB) at the chosen study sites in Belgium. IRB approval is the final approval required before trial initiation.

Prima's CSO & CMO, Dr. Frédéric Triebel said, 'Prima BioMed has, over the last 10 months, assembled a first class team to work on AIPAC. The clearing of our study protocol by FAMHP represents a big step forward for the team and we are on track to commence the study by the end of 2015.'

AIPAC - A key study

IMP321, a first-in-class Antigen Presenting Cell (APC) activator based on the immune checkpoint LAG-3, represents one of the first proposed active immunotherapy drugs in which the patient's own immune system is harnessed to respond to tumour antigenic debris created by chemotherapy. As an APC activator IMP321 boosts the network of dendritic cells in the body that can respond to tumour antigens for a better anti-tumour CD8 T cell response.

IMP321 has been shown in an open-label Phase I study[1] to be able to double the expected six-month response rate in HER-2 negative metastatic breast cancer patients receiving standard-of-care paclitaxel, from a 25% historic response rate[2] (RECIST criteria) to 50% when combined with

[1] See Brignone et.al., J. Transl. Med. 2010, 8:71.
[1] Miller et. al., N. Engl. J. Med. 2007, 357: 2666-76.

IMP321. AIPAC has been designed to confirm this expected response and evaluate its effect on patient survival in a randomized, double blind, placebo-controlled setting and in a comparable patient population. Progression-Free Survival (PFS) will be AIPAC's primary endpoint. RECIST response rates and Overall Survival are among the secondary endpoints. The design of the study has been examined by the EMA's Scientific Advice expert panel in the view of using these data for Marketing Authorization in the EU in tested setting.

The protocol that arose from Prima's interaction with the EMA will see women recruited into AIPAC with metastatic breast cancer where the tumour is HER-2-negative but hormone receptor positive. These patients will be receiving paclitaxel as first line chemotherapy after having failed on hormone therapy. They will represent a large patient population (hormone receptor-positive breast cancer is accounting for app. 75 percent of all cases) for which there are few viable treatment options, as indicated by the fact that PFS in such patients can be as low as six months[3].

In the AIPAC study, patients will be administered subcutaneous doses of IMP321 on days 2 and 16 of a weekly regimen of paclitaxel, the day after their paclitaxel infusion.

AIPAC will aim to initially recruit 15 patients for a smaller safety run-in in three different countries. This section of the trial will test in combination with paclitaxel the safety of IMP321 in doses up to 30 mg per dose, which has previously been shown to be safe when tested as a monotherapy[4] and is significantly higher than the maximum 6.25 mg dose from the Phase I in metastatic breast cancer. This section of AIPAC, extending into 2016, and will yield valuable safety, pharmacokinetic and pharmacodynamic data that Prima expects to report in second half of 2016.

After the safety run-in the AIPAC investigators will proceed to recruit 196 patients, randomising them 1:1 to either standard-of-care paclitaxel plus placebo or paclitaxel plus IMP321 for six months as per the Phase I dosing regimen, after which the responding or stable patients will be maintained for another year with monthly IMP321 injections. The study has been powered to show a four-month PFS advantage for the treatment group. Allowing time for patient recruitment and follow-up, AIPAC's expected duration is around three years. Throughout the study, an independent data monitoring committee will review patient safety, survival rates and demographics at regular intervals. No interim statistical analysis is planned.

Prima envisages setting up at least 30 study sites for AIPAC in six European countries – starting with Belgium, France and the Netherlands. While Belgian regulatory approval has now been received for AIPAC, the relevant approvals are still to be obtained for the other countries.

About Prima BioMed

Prima BioMed is a globally active biotechnology company that is striving to become a leader in the development of immunotherapeutic products for the treatment of cancer. Prima BioMed is

[3] Miller et. al., op. cit.

[3] See Brignone et.al. Clin. Cancer Res. 2009, 15:6225-31.

dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Prima's current lead product is IMP321, based on the LAG-3 immune control mechanism which plays a vital role in the regulation of the T cell immune response. IMP321, which is a soluble LAG-3Ig fusion protein, is an APC activator boosting T cell responses for cancer chemo-immunotherapy and in other combinations which has completed early Phase II trials. A number of additional LAG-3 products including antibodies for immune response modulation in autoimmunity and cancer are being developed by large pharmaceutical partners.

Prima BioMed is listed on the Australian Stock Exchange, and on the NASDAQ in the US. For further information please visit www.primabiomed.com.au.

For further information please contact:

Prima BioMed Ltd:
Stuart Roberts
+61 (0) 447 247 909; stuart.roberts@primabiomed.com.au

Australia Investor/Media:
Mr Matthew Gregorowski, Citadel Communications
+61 (0) 422 534 755; mgregorowski@citadelpr.com.au